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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LANDREM, KAMRIN R	
ART UNIT	**PAPER NUMBER**
3738	12

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/022,607	DING ET AL.
	Examiner	**Art Unit**
	Kamrin R. Landrem	3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 26 January 2004.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-29 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 8, 10-12, 14, 19, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff et al. (USPN 5,545,208) in view of Hossainy et al (USPN 6,558,733 B1).

Wolff, as discussed in the previous office action, discloses an expandable (by balloon or self-expanding, Column 10) metal stent with openings (Figure 1) with a coating of hydrophobic biostable elastomeric material (6:60-63) and a biologically active material or drug such as Heprin (5:41) that conforms to the structure and preserves the openings of the stent (Figures 12 and 13). Wolff discloses the expandable stent as claimed however Wolff fails to teach that the stent is prefabricated before it is coated. Hossainy et al teaches the method of producing a drug delivering stent by using a prefabricated (11:37) stent 10 that is etched and then coated with therapeutic substances (4:37+) to provide a stent with improved drug delivery capabilities. Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the method disclosed by Hossainy by using a prefabricated stent to produce the coated expandable stent as disclosed by Wolff.

Claims 2, 4, 5, 13, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff as modified by Hossainy, further in view of Lambert (USPN 5,900,246).

Regarding claim 2, Wolff, as modified, discloses of a prefabricated stent that is coated but lacks the teaching of the thickness and composition of the coating. Lambert teaches of a stent with a polyurethane coating that has a thickness between 25 and 500 microns to vary the degree of swelling of the coating for drug release (Column 4, lines 27-30), overlapping the ranges disclosed by the applicant. Lambert further teaches that the composition of the polymer coating can have a 1:20 or 5% ratio of solvent to non-solvent to achieve the desired rate of evaporation (Column 4, lines 36-52), falling within the 4 to 6% range disclosed by the applicant. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Wolff to specify the thickness and composition of the coating in order to account for swelling and solubility of the compounds within the coating.

Claims 6, 7, 9, 17, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff as modified by Hossainy, further in view of Berg et al. (USPN 5,464,650).

Regarding claims 6, 7, 9, 17, 18 and 20 Wolff as modified discloses a prefabricated stent that is coated, however they lack the teaching of how the stent is coated. Berg et al. teach of a stent made of tantulum or stainless steel (Column 3, Lines 35-40) that is coated by a spraying method while being rotated (Column 5, Example 1). Berg et al. further teach that the stent is coated while in the expanded position (Column 6, Example 7). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Wolff et al. to have the metallic stent made of stainless steel, titanium or another

metal for strengthened physical properties, and to coat the stent while rotating it in an expanded state to ensure a coating of even thickness.

Claims 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert (USPN 5,900,246) in view of Hossainy.

Lambert discloses a metallic stent (3:51) that has a coating of 25 to 500 microns in thickness (4:28), comprising a biostable elastomeric material (polyurethane) and a biologically active material (dexamethasone) (Column 3). Lambert discloses the stent as claimed however Lambert fails to teach that the stent is prefabricated. Hossainy teaches an expandable prefabricated (7:57) metal (4:18-22) stent 10, that is coated with a biologically active material (4:38+), having a tubular body and a sidewall structure having openings (see Figures 1-4), the openings free from any coating. Therefore in view of the teachings it would have been obvious at the time the invention was made to have modified the stent as disclosed by Lambert by using a prefabricated stent with openings free of coating as taught by Hossainy in order to provide a stent with improved drug delivery properties that allows for tissue ingrowth.

Regarding claims 26-28, Lambert teaches of a coated stent, however Lambert lacks the teaching of the process by which the stent is coated. However, the final product, a coated stent, is taught in the prior art and therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the claimed coating process to apply a coating to the stent for anti-inflammatory purposes (see MPEP 2113).

Response to Arguments

Applicant's arguments filed November 26, 2003 have been fully considered but they are not persuasive. Wolff et al anticipate the applicant's claimed stent of independent claims 1 and 12. The end product is the same and Hossainy is used as a teaching to disclose that stents are prefabricated then coating applied. Hossainy is not used to teach a particular coating method or process but instead to teach coating a stent that is prefabricated. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." (MPEP 2113).

The applicant's claimed stent in independent claim 23 is disclosed by Lambert in view of Hossainy. Lambert discloses a metallic stent that has a coating of 25 to 500 microns in thickness (4:28), comprising a biostable elastomeric material (polyurethane) and a biologically active material (dexamethasone) (Column 3). Hossainy is used to teach an expandable Nitinol stent that is prefabricated before any coating takes place. Again the combination of Lambert and Hossainy produces the product as claimed. The patentability of the applicant's stent is based on the product itself, not the process by which it is formed.

Conclusion

This is a continuation of applicant's earlier Application No. 10/022,607. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamrin R. Landrem whose telephone number is 703-305-8061. The examiner can normally be reached on 8:00-5:00, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kamrin Landrem
Examiner
AU 3738

krl

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